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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,097	04/13/2004	Cynthia C. Bamdad	M1015.70013US01	3158

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,097

Applicant(s)

BAMDAD ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 5, 10, and 26, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 485-504 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 485-504 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry and Claim Status

The preliminary amendments filed on January 05, 10 and 26, 2006 have been acknowledged and entered.

Claims 485-504 are pending. All other claims are cancelled.

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 485-504 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 485 is unclear of what the means for determining the immobilization of the first to second colloidal particle. Does the binding of the biological species give off some sort of signal when they become bound to each other therefore determining that the first colloidal particle is immobilized to the second colloidal particle?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 485 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/763,810 ('810). Although the conflicting claims are not identical, they are not patentably distinct from each other because Application '810 claims a method of exposing a first surface or region or a surface carrying a first immobilized component and a second surface or region of a surface carrying a second immobilized components to colloidal particles carrying immobilized species and determining immobilization of the colloidal particles to the first or second surface or region. The first and second surface or region can be of another colloidal particle. Thus, the method of application '810 has the same purpose of determining immobilization of the colloidal particles to the first or second surface or region of the other colloidal particles.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 485 is rejected under 35 U.S.C. 102(b) as being anticipated by Liberti et al. (US 5,108,933).

Liberti teaches manipulating colloids via magnetic separation. The method is using a first colloidal protein magnetite (first colloidal particle coated with first protein) and a second colloidal protein magnetite having a binding affinity for a determinant on the first colloidal protein magnetite. (see col. 18, line66-col. 19, line 2). Separation takes place before determining the immobilization of the first colloid particle with respect to the second colloidal particle. (see col. 18, lines 44-46).

Claim 485 is rejected under 35 U.S.C. 102(b) as being anticipated by Masson et al. (US 4,279,617).

Masson teaches a particle agglutination assay for antigens, antibodies and other binding proteins using two different, microscopic or submicroscopic particulate reagents. The first particulate reagent binds with the antigen or antibody under assay, and then the second particulate reagent which has a specific binding member attached thereto is added which binds only to those first reagent particles which have bound to the antigen or antibody under assay, so causing agglutination. The free unbound first and second particles are assayed to indicate the presence and/or amount of the antigen/antibody under assay. (see abstract, col. 1, line 64-col. 2, line 67; col. 4, lines 59-63).

Determining the immobilization of the first and second particles is equivalent to the counting of the non-bound particles. The specification of the present invention describes that colloidal particles are nanoparticles including inorganic, organic, polymeric,

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ceramic, semiconductor, metallic (gold), non-metallic, etc. (see page 22, lines 4-11).

The particles of Masson are latex which are less than 15 microns. (col. 2, lines 31-35).

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 503 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 503 is confusing because it is unclear how the first and second species can bind with the presence of the enzyme and enzyme substrate and the agent suspected of inhibiting enzyme. The enzyme and the enzyme substrate would bind to each other and such binding gives off signal. However, regardless whether the enzyme binds to the substrate, the two species would bind to the common entity (enzyme substrate) anyways. What good is the enzyme when the two species bind to the enzyme substrate and the colloidal particles would give off signal anyways?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 485-487, 489, 492-502 and 504 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirkin et al. (US 6,984,491).

Mirkin teaches a method of immobilizing colloid particles comprising allowing a first nanoparticle (colloid) conjugated to first oligonucleotides and a second nanoparticle (colloid) conjugated to second oligonucleotides to bind to each other via the binding of first and second oligonucleotides. (see col. 4, line 65-col. 5, line 18). With respect to claims 486 and 487, Mirkin teaches that gold particles may be attached to oligonucleotides using biotin-labeled oligonucleotides and streptavidin-gold conjugate (affinity tag interaction). (see col. 130, lines 9-55). Mirkin also teaches that the gold particles can be functionalized with carboxylic acids (carboxylate group) (see col. 38 line 64). With respect to claim 489, the oligonucleotides interaction is a biological interaction. With respect to claim 492, oligonucleotides are synthetic molecules. (example 17). With respect to claim 493, the nanoparticles are gold colloid particles. (see col. 71, line 34). With respect to claims 494 and 495, Mirkin teaches that the oligonucleotides on either nanoparticles are labeled with an energy acceptor or donor which are fluorescent molecules (equivalent to emissive or absorptive species of the claimed invention). (see col. 7, line 30). With respect to claims 496, 498, 500, and 504, Mirkin teaches that the first oligonucleotides have a sequence complement to a first portion of the sequence of a target nucleic acid, and the second oligonucleotides have a sequence complement to a second portion of the sequence of the target nucleic acid. The nucleic acid is contacted with the two types of nanoparticles having first and second oligonucleotides

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under conditions for hybridization of the oligonucleotides with the nucleic acid. (common entity-biological material). (see col. 4, line 65-col. 5, line 18). The nucleic acid forms a aggregate of the two nanoparticles. Thus, it is an aggregate forming species. With respect to claim 497, Mirkin teaches the two binding species bind to a common entity which is a colloid particle in figure 13B, the aggregate of nanoparticles. With respect to claims 499 and 501, Mirkin teaches the analyte is a drug (see col. 27, lines 10-12). With respect to claim 502, Mirkin teaches that the analyte can be an enzyme. (see col. 27, lines 40-42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 490 and 491 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin et al. (US 6,984, 491).

Mirkin has been discussed above for teaching the present invention except that the first and second species are protein and that the binding interaction is between a protein and a nucleic acid.

Mirkin discusses on col. 1, lines 55-60, that methods have been reported for making nanoparticles (Quantum dots) water soluble, allowing the immobilization of protein structure on the quantum dot surface. One involves encapsulation of the core-shell structures with a silica layer.

Thus, it would have been obvious to one of ordinary skills in the art to immobilize protein on the nanoparticles and allow the proteins to bind to each other to form aggregate or to bind to a common entity such as a nucleic acid to study protein-protein interaction of a sample in order to diagnose a disease or condition.

Claim 488 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin in view of Went (US 6,150,179).

Mirkin has been discussed above.

However, Mirkin fails to teach that the species fastened to the colloid particle via a metal binding tag.

Went teaches incorporate metal affinity binding tag such as His-tag into proteins so that the proteins can bind to solid phase. (see col. 20, lines 39-40; col. 58, line 49).

It would have been obvious to one of ordinary skills in the art to use the metal binding tag taught by Went as an affinity binding tag to bind the oligonucleotides or proteins to the nanoparticles because the nanoparticles are metals and thus such tag would bind with high affinity to the nanoparticles since it is a metal binding tag.

Response to Arguments

Applicant's arguments filed January 5, 10 and 26, 2006 have been fully considered but they are not persuasive.

With respect to the rejections by Liberti and Masson, Applicants argue that Liberti and Masson fail to disclose using a signaling entity sub-micron particle for the detection of various biological components in a sample. Further, Liberti and Masson

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disclose particles which are not coated with self-assembled monolayer; and these particles have no signaling ability.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., signaling entity, self-assembled monolayer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The present claims fail to recite a signaling entity nor the particles being coated with a self-assembled monolayer. Thus, *Liberti* and *Masson* are still applicable.

Remark

Claim 503 is free of prior art as now recited.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
August 31, 2006


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